Objective Measures of Functional Outcome in Recovery from Open Lower Limb Fractures – A Report from an Ortho-Plastic Research Clinic

Pallister I (ianpallister@hotmail.com)
Swansea University Medical School https://orcid.org/0000-0002-0570-1012

Gregory Jack Handley
Morriston Hospital

Sharon Maggs
Morriston Hospital

Ann-Marie Davies
Morriston Hospital

Amanda Kyle
Morriston Hospital

Owen Bodger
Morriston Hospital

Hywel Dafydd
Morriston Hospital

Research article

Keywords: Open lower limb fractures, outcome, recovery, rehabilitation, function, complications

Posted Date: May 5th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-24944/v1

Abstract

BACKGROUND

Open lower limb fractures are serious, potentially life-changing injuriesrequiring combined ortho-plastic surgery and have significantly worse outcomes than similar closed fractures. There is little objective published data to determine which functional outcome measures best reflect progress or completeness of physical recovery.

Our hypothesis was that objective measures combining strength, agility and balance would better reflect recovery than isolated parameters (e.g. range of motion) and would compare well to patients' perceived recovery.

METHODS

Adultopen lower limb fracture patients were followed-up at 6 and 12 weeks, 6, 9 and 12 months post-injury. The mechanism,injurypattern, age, gender and treatment were recorded. Isolated parameter objective functional outcome measures (OFOMs)(range of movement and MRC strength grade) were compared to combined OFOMs(timed up and go (TUAG), comfortable and fast gait speed (CGS and FGS), Edgren Side Step Test(ESST) and Single Leg balance. Patient reported outcomes were recorded (Global Perceived Effect (GPE) scoreand Disability Rating Index (DRI)).

RESULTS

68 patients (54 male) with a medianage of 45 years (range 20-75). Neither range of movement,strength nor Single Leg balance consistently improved with time. TUAG, ESST, CGS, FGS and GPE scoresshowed consistent improvement, with TUAG and FGS showing highest proportion of improving results at each time-point. Patients' estimation of recovery paralleled these measures with all but 2 patients achieving the minimum clinical important difference in DRI by 12 months compared to baseline. However, the GPE score compared favourably withthe DRI having a higher proportion of improving responses at each time-point.

DISCUSSION

Functional recovery is a key determinant in patients returning to work, providing for themselves and their family or resuming independent living for older patients. This study has demonstrated time-related improvements in combined OFOMs measuringmobility, strength, agility and balance paralleling patients' perception of recovery in the 12 months after open lower limb fractures. Over the same time-frame, the simple GPE score compared favourably with the DRI. Such parameters could become part of a defined core outcomes set. Focussing rehabilitation towards these combined OFOMs may help hasten recovery.

Trial registration

South West Wales REC 06/WMW02/10)

Background

Open lower limb fractures are serious and potentially life-changing injuries, often requiring combined orthopaedic and plastic surgical management in specialist units(1, 2). Following surgery, rehabilitation to minimise swelling, scarring and promote independent mobility is vital. Even when the limb is preserved and wound and bone healing are complete, a wide range of clinical outcomes are seen, ranging from pain free mobility and a return to manual work, to ongoing pain, troublesome disfiguring scarring and problems with mobility. This distinguishes recovery from open lower limb fractures from their closed counterparts. Indeed, disability rating index (DRI) scores at 12 months post injury are distinctly worse in open fracture patients compared to those with closed fractures (3, 4). For these reasons the need for a defined core outcome set for open lower limb fractures has been recognised (5). This would enable the meaningful comparison of surgical strategies within and between future studies.

In recent years, interest has grown in the value of Patient Reported Outcomes Measures (PROMS) as distinct from the measures of technical success such as wound or bone healing, alignment and the number and complexity of reconstructive surgical procedures. However, there is little objective published data to determine which functional outcome measures best reflect either patient progress or completeness of their physical recovery.

As part of a larger project studying recovery from open lower limb fractures, the potential benefits of functional recovery measures that reflect strength, agility and endurance became apparent (Wales Lower Limb Trauma Recovery Project (WaLLTR) South West Wales REC 06/WMW02/10). These measures have been studied extensively in stroke rehabilitation, recovery from hip fracture and also sports medicine (6–9). Given the paucity of data with respect to these combined measures in the open lower limb fracture population, a pragmatic decision was required to select a range of measures to be studied (10).

An observational study was conducted of the objective functional outcome measures recorded in adult open lower limb fracture patients attending the Morriston Hospital Ortho-Plastic Trauma Research Clinic (OPRC) and these findings were correlated with the passage of time from injury and the Disability Rating Index (DRI) (5, 11–13).

The aim of the study was to determine whether objective functional outcome measures (OFOMs) mirrored changes in health-related quality of life patient reported outcome measures with the passage of time. Our hypothesis was that measures of combined strength, agility and balance would better reflect recovery than isolated parameters such as range of motion.

Methods

Adult patients (aged 16–80) were identified during their recovery from open lower limb fractures which had required Ortho-Plastic management in Morriston Hospital, Swansea UK. They were approached and enrolled in the WaLLTR Study after informed consent was obtained. Follow-up in OPRC was scheduled at 6 and 12 weeks, 6, 9 and 12 months post-injury. A battery of objective functional outcome measures was

identified at the inception of the clinic, including range of movement (degrees) and MRC strength grade (0–5) at the hip, knee and ankle on both lower limbs (14–16).

Combined strength, agility and balance were determined as follows. The “Timed Up & Go” (TUG) Test was recorded as the time taken to stand up from a seated position in a chair, walk straight for 3 m, turn 180°, walk back to the chair, then sitting down (8). Completing this exercise in 10 seconds or less is regarded as normal mobility, 30 seconds or more reflecting significantly impaired mobility. The Comfortable Gait Speed (CGS) and Fast Gait Speed (FGS) were determined by measuring the walking speed in the middle 10 m of a 14 m straight line after asking the participant to “Walk at your preferred walking speed as if you were walking in a park” (CGS) and “Walk as fast and as safely as you can” (FGS) respectively (7).

The Edgren Side Step Test (ESST: metres) quantifies an individual’s agility in the lateral direction. Four cones are placed in a line each 1 m from its neighbour (9). The participant then side-steps back and forth to the outside cone as rapidly as possible for 10 seconds. Balance as a discrete parameter was assessed using the Single Leg Stand Test (SLS: seconds) (17). The length of time for which a participant balanced on the required leg (without the other lower limb touching and with their arms by their sides) was recorded, up to a maximum of 30 seconds.

The Global Perceived Effect score was recorded on a 0-100 mm linear scale, with none of their previous scores being visible to the patient. It was explained that the scale represented them at their very worst immediately following their injury (zero), to being restored to completely back to their former selves (100 mm) (18–21).

The Disability Rating Index (DRI) was also recorded at each timepoint. The scale runs from 100 (worst) to zero (best); the minimum clinically important difference (MCID) in the DRI is 8 points (3, 12) .

These data were analysed in terms of data completeness and time related changes, in particular the number of individuals whose results had changed (improved or worsened) between measurements.

Results

In all, 79 patients enrolled although 2 patients subsequently withdrew their consent and a further 9 patients did not attend the OPRC and were lost to research follow-up. The remaining 68 patients had sustained 70 open lower limb fractures and were enrolled from 15/04/2014 to 25/08/2017 and followed up for 12 months. Fifty-four patients were male with a median age of 45 years (range 20–74). Fifteen patients were female with a median age of 51 years (range 22–73). The mechanism of injury, AO fracture and Gustilo-Anderson classification are summarised in table 1. The type of definitive fracture fixation and soft tissue repair is shown in table 2.

Mechanism of Injury		AO/OTA Fracture Type		Gustilo-Anderson Classification	
Crush Injury	5	Femoral Shaft 32	2	I	13
Occupant RTC	3	Tibia- Proximal metaphysis 41	5	II	-
Motorcycle RTC (Bicycle)	14 (1)	Tibial Shaft 42	34	IIIA	11
Pedestrian RTC	11	Tibia- Distal metaphysis 43	14	IIIB	44
Fall from Height	14	Ankle 44	13	IIIC	1
Fall from Standing	11				

Table 1:

Method of Fixation		Mode of Soft Tissue Cover	
CIRCULAR FRAME	8	Primary Closure	13
Intramedullary Nail (Hind Foot Nail)	37 (1)	Split Skin Grafting only	18
ORIF	23	Fasciocutaneous Flap	18
Amputation	1	Local Muscle Flap	9
Masquelet	1	Free Tissue Transfer	16
Transport	1	Papineau	1

Table 2:

The most common mechanism of injury was due to road traffic collisions, followed by falls from a standing height. Crush injuries were sustained by 5 individuals. The Gustilo-Anderson Grade was determined definitively at the time of surgical treatment with Type I 13, IIIA 11, IIIB 44, IIIC 1. The soft tissue injury associated with the IIIC injury warranted only split skin grafting. The commonest location of the open fracture was tibia shaft (34/68) and the most frequently employed means of definitive stabilisation was an intramedullary nail (37/68). Thirteen patients had wounds suitable for primary closure, 27 were treatable using local flaps and 16 required reconstruction using free tissue transfer; one

primary amputation was required. One patient was managed using open cancellous bone grafting (Papineau technique) and another using induced membrane formation (Masquelet technique) (22, 23).

One patient who had originally undergone intramedullary nail fixation and anterolateral thigh flap coverage required revision to a below knee amputation during the original admission due to flap failure and the lack of any suitable salvage procedure.

Three patients required revision intramedullary nailing at approximately 3, 7 and 11 months post injury for correction of alignment. Two had preceding problems with wound healing but none had evidence of deep infection on intraoperative cultures.

Neither range of movement nor MRC strength grade showed consistent improvement with time. Representative data for active ankle dorsiflexion is shown in Fig. 1 showing the median (interquartile and range) and mean (95% CI) along with the proportion of repeated assessments which improved, worsened or remained unchanged. Similar results were obtained for all measures of range of motion and MRC power in the affected limb. Single Leg Stand appeared to improve to 6 months but no significant correlation was demonstrated.

Comfortable and fast gait speed, Edgren Side Step Test and Timed up and go showed consistent improvement with the passage of time (Spearman's rho 2-tailed correlation significant at $p < 0.01$ level). These data are presented in Fig. 2 panels a-d respectively with the panels in each figure following the same pattern as that for Fig. 1.

Patients' reported outcomes reflected in their GPE score and DRI also showed consistent improvement with time, as shown in Fig. 3. The DRI minimum detectable change has been recognised as +/-2.7 and so "no change" in this figure reflects responses within this range rather than being simply numerically equal. All but 2 patients DRI score had improved by the MCID of 8 + points between the baseline and 12 month assessments. However, the GPE score compared favourably with the DRI, with a higher proportion of improving responses at each time-point.

Discussion

We hypothesised that improvements in objective outcome measures combining strength, agility and balance would mirror patients' own perceptions of their recovery after open lower limb fractures. There is a paucity of published data to establish reliable core clinical outcome measures in this group of patients (5, 24). Open lower limb fractures can be life-changing injuries. Even when complication rates are low, a recent randomised multi-centre study has shown significant levels of patient reported disability throughout the first 12 months post-injury (3, 25, 26). In this study of 427 patients who completed the trial, DRI scores improved from the mid-sixties at 3 months to mid-forties at 12 months. By comparison, the DRI score of patients with closed distal tibial fractures were distinctly better with average scores in the low 20 s, around double the MCID for this measure (4).

Qualitative research has thrown light on patients' experiences and perceptions of the impact of open lower limb fractures, which extend far beyond the obvious physical consequences (3, 13, 25). Nevertheless, functional recovery is the key determinant in patients being able to return to work and provide for themselves and their family or resume independent living for older patients. A painless limb free of contractures may lack the strength, proprioception and endurance necessary to undertake everyday activities. This study has demonstrated a clear relationship between combined measures of strength, agility and balance with patient reported measures of recovery and health-related quality of life collected in parallel in the 12 months after open lower limb fractures. Focussing rehabilitation towards improvement in these combined measures may help hasten recovery.

Isolated parameter objective functional outcomes measures did not show any consistent improvement with the passage of time. In a previous observational study, ankle dorsiflexion at the time of cast removal in post-ankle fracture patients has been associated with better recovery quantified by Olerud and Molander ankle score, the Lower Extremity Functional Scale and also the Global Perceived Effect score (GPE) six weeks and six months later (15). While the lunge weight-bearing method to measure dorsiflexion may be very reliable (14), it cannot be used effectively in those unable to fully weight-bear. In this study, patients with articular fractures (AO 43B/C and AO 44 n = 22) were advised to be non-weight-bearing for 6 weeks and then incrementally increase to be fully weight-bearing by 12 weeks.

Gait speed is a recognised form of assessment in patients following stroke and hip fracture, with faster gait speeds associated with greater degrees of independence and mobility (27). Speeds greater than 1.2 m/s are considered normal, 0.8–1.2 m/s community ambulators, 0.4–0.8 m/s limited community ambulators and walking speeds lower than this leading to the patient essentially being housebound. In Fig. 2a it can be seen that by 9 months, approximately 75% of the patients completing the assessment were comfortable walking at a pace of 1 m/s or faster.

Comfortable and maximum gait speeds have been assessed in healthy individuals and stratified according to gender, height and age (7). Gender had little demonstrable effect, however gait speed did correlate with muscle strength, in particular hip abductors for comfortable gait speed and knee extensors for maximum gait speed. Comfortable gait speed declined slowly with increasing age from 20th to 70th decades (mean 1.4 m/s – 1.3 m/s) and maximum gait speed more sharply (mean 2.5 m/s – 1.9 m/s). In this study population, Fig. 2(b) shows that by 6 months approximately 75% of patients completing the assessment achieved a fast gait speed of 1 m/s or greater. By 12 months post injury, over half the patients could sustain a speed of 1.5 m/s. At 12 months, only 9 patients had TUAG times greater than 10 seconds, indicating normal mobility as determined by this test, although none exceeded 18 seconds.

In terms of patient reported outcome, the use of the GPE scale in the manner described yielded responses specific to the injury itself, inviting comparison of themselves at their worst immediately after injury versus how they were at their best beforehand. The responses elicited using the DRI gave medians comparable to those reported previously (approximately 60 at 3 months recovering to 40 at 12 months) but with a wide range of responses. The lack of consistent improvement with time for individual patients

suggests that this score may be better restricted to studies of populations at defined and well separated timepoints, rather than being used as a “monitoring” score with serial measurements taken only a few months apart.

This study has limitations. Not all patients sustaining lower limb fractures will have been identified for potential enrolment. A very small proportion of those approached declined consent to attend the OPRC. Of those who did, few were able to attend every single appointment and so the data is inevitably incomplete. Nevertheless the results obtained are consistent across the population studied. No comparison has been made with recovery in patients with comparable closed fracture types. Available resources did not permit this, although the log-term goal of the project is to extend this approach to closed fracture patients. While such a comparison would have been of interest, published data and clinical experience would strongly suggest that these injuries are distinctly different in their outcomes, as well as surgical strategy {Costa, 2018 #52; Costa, 2017 #121}.

Determining outcomes in healthcare has moved beyond measuring the frequency of technical problems or achievements. Patients with deep infection or non-union after open fractures will require further management and so those complications may be better regarded not as outcomes, but events along the road to recovery. PROMS, even if derived from the specific patient population under review, will introduce an element of subjectivity. However patients’ perception of their recovery is essential in completing the picture. Functional recovery is vital as this will determine independence, resumption of caring for their family and return to work, all of which are so important in sustaining an individual’s self-worth. Identifying objective functional outcome measures which mirror patients’ perception of recovery has great value in helping to focus rehabilitation and forming part of a set of core clinical outcomes for future research.

The ideal outcome measures for these severe (and indeed many less severe) injuries are yet to be determined. In a recent workshop involving patients, their family members, researchers and clinicians, walking ability/mobility was identified as a key outcome after open lower limb fractures (28). The objective measures described here were originally developed with patients whose mobility was impaired in mind. Further research is needed to refine these measures or develop new ones which reflect recovering mobility more precisely. In this way, a future core outcomes set will enable surgical strategies within and between studies to be meaningfully compared.

Declarations

Ethics approval was obtained prospectively (South West Wales REC 06/WMW02/10). No identifiable patient data or images are presented.

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

The authors declare that they have no competing interests.

Funding was obtained from the AO Foundation and the Osteosynthesis and Trauma Care Foundation. These funding bodies had no role in the design of the study, data collection, analysis, and interpretation nor did they have a role in writing the manuscript.

All of the authors contributed in terms of data collected, collation and preparation, and all contributed to the writing and review of the submitted manuscript.

The authors gratefully acknowledge the help and support provided by Anne-Claire Owen, Jemma Hughes and Mark Simpson, Research & Development, Swansea Bay University Health Board for continued administrative and financial support. Also, the Physiotherapy and Occupational Therapy services at Swansea Bay University Health Board. And last but not least the Clinical Research Unit, Joint Clinical Research Facility, Morriston Hospital, Swansea.

References

1. (UK). NCGC. Fractures (Complex): Assessment and Management.Open fractures. London: National Institute for Health and Care Excellence (UK); 2016 [updated 2016 cited]; Available from: https://www.ncbi.nlm.nih.gov/books/NBK368199/.
2. Nanchahal J, Nayagam N, Khan U, Moran C, Barrett S, Sanderson F, et al. Standards for the management of open fractures of the lower limb. British Association of Plastic Reconstructive and Aesthetic Surgeons. British Orthopedic Association. 2009.
3. Costa ML, Achten J, Bruce J, Tutton E, Petrou S, Lamb SE, et al. Effect of negative pressure wound therapy vs standard wound management on 12-month disability among adults with severe open fracture of the lower limb: The WOLLF randomized clinical trial. JAMA. 2018;319(22):2280-8.
4. Costa ML, Achten J, Griffin J, Petrou S, Pallister I, Lamb SE, et al. Effect of Locking Plate Fixation vs Intramedullary Nail Fixation on 6-Month Disability Among Adults With Displaced Fracture of the Distal Tibia: The UK FixDT Randomized Clinical Trial. JAMA. 2017;318(18):1767-76.
5. Morris R, Pallister I, Trickett RW. Measuring outcomes following Tibial Fracture. Injury. 2018.
6. Binder EF, Brown M, Sinacore DR, Steger-May K, Yarasheski KE, Schechtman KB. Effects of extended outpatient rehabilitation after hip fracture: A randomized controlled trial. JAMA. 2004;292(7):837-46.
7. Bohannon RW. Comfortable and maximum walking speed of adults aged 20-79 years: reference values and determinants. Age and Ageing. 1997;26(1):15-9.
8. Hiengkaew V, Jitaree K, Chaiyawat P. Minimal detectable changes of the Berg Balance Scale, Fugl-Meyer Assessment Scale, Timed “Up & Go” Test, gait speeds, and 2-minute walk test in individuals with chronic stroke with different degrees of ankle plantarflexor tone. Archives of physical medicine and rehabilitation. 2012;93(7):1201-8.
9. Raya MA, Gailey RS, Gaunaurd IA, Jayne DM, Campbell SM, Gagne E, et al. Comparison of three agility tests with male servicemembers: Edgren Side Step Test, T-Test, and Illinois Agility Test. J Rehabil Res Dev. 2013;50(7):951-60.

10. Morris R, Maggs S, Bodger O, Pallister I. Monitoring recovery of open tibial fractures using objective functional measures with preliminary data from a combined orthoplastic research clinic. Canadian Journal of Surgery. 2016;59(3 Suppl 1):S8.
11. Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of Life Research. [journal article]. 2011 December 01;20(10):1727-36.
12. Salen BA, Spangfort EV, Nygren AL, Nordemar R. The disability rating index: An instrument for the assessment of disability in clinical settings. Journal of clinical epidemiology. 1994 2018/02/09;47(12):1423-35.
13. Trickett RW, Mudge E, Price P, Pallister I. A qualitative approach to recovery after open tibial fracture: the road to a novel, patient-derived recovery scale. Injury. 2012;43(7):1071-8.
14. Bennell K, Talbot R, Wajswelner H, Techovanich W, Kelly D, Hall A. Intra-rater and inter-rater reliability of a weight-bearing lunge measure of ankle dorsiflexion. Australian Journal of physiotherapy. 1998;44:175-80.
15. Hancock M, Herbert R, Stewart M. Prediction of Outcome After Ankle Fracture. J Orthop Sports Phys Ther. 2005;35:786-92.
16. Council MR. Aids to the Examination of the Peripheral Nervous System (Memorandum No. 45). Her Majesty's Stationary Office; 1976.
17. Vellas BJ, Wayne SJ, Romero L, Baumgartner RN, Rubenstein LZ, Garry PJ. One leg balance is an important predictor of injurious falls in older persons. Journal of the American Geriatrics Society. 1997;45(6):735-8.
18. Kamper SJ, Ostelo RW, Knol DL, Maher CG, de Vet HC, Hancock MJ. Global Perceived Effect scales provided reliable assessments of health transition in people with musculoskeletal disorders, but ratings are strongly influenced by current status. Journal of clinical epidemiology. 2010;63(7):760-6. e1.
19. Cook CE. Clinimetrics Corner: The Minimal Clinically Important Change Score (MCID): A Necessary Pretense. The Journal of manual & manipulative therapy. 2008;16(4):E82-E3.
20. Lin C-WC, Moseley AM, Haas M, Refshauge KM, Herbert RD. Manual Therapy in Addition to Physiotherapy does not Improve Clinical or Economic Outcomes After Ankle Fracture. Journal of Rehabilitation Medicine. 2008;40(6):433-9.
21. Weiss R, Montgomery S, Ehlin A, Al Dabbagh Z, Stark A, Jansson K. Decreasing incidence of tibial shaft fractures between 1998 and 2004: information based on 10,627 Swedish inpatients. . Acta Orthop. 2008;79(4):526-33.
22. Archdeacon MT, Messerschmitt P. Modern papineau technique with vacuum-assisted closure. Journal of orthopaedic trauma. 2006;20(2):134-7.
23. Morris R, Hossain M, Evans A, Pallister I. Induced membrane technique for treating tibial defects gives mixed results. The Bone & Joint Journal. 2017;99(5):680-5.

24. Morris R, Jones NC, Pallister I. The Use of Personalised Patient Information Leaflets to Improve Patients' Perceived Understanding Following Open Fractures
25. EJOS. 2018.
26. Tutton E, Achten J, Lamb SE, Willett K, Costa ML. A qualitative study of patient experience of an open fracture of the lower limb during acute care. The Bone & Joint Journal. 2018;100-B(4):522-6.
27. Young K, Aquilina A, Chesser TJS, Costa ML, Hettiaratchy S, Kelly MB, et al. Open tibial fractures in major trauma centres: A national prospective cohort study of current practice. Injury. 2018 Oct In Press.
28. Fritz S, Lusardi M. White Paper: Walking Speed: the Sixth Vital Signâ€. Journal of Geriatric Physical Therapy. 2009;32(2):2-5.
29. Costa M, Aquilina A. Core Outcomes for research on Open Lower Limb Fractures (CO-OLLF): Development of a core outcome set and core outcome measurement set 2019.

Figures

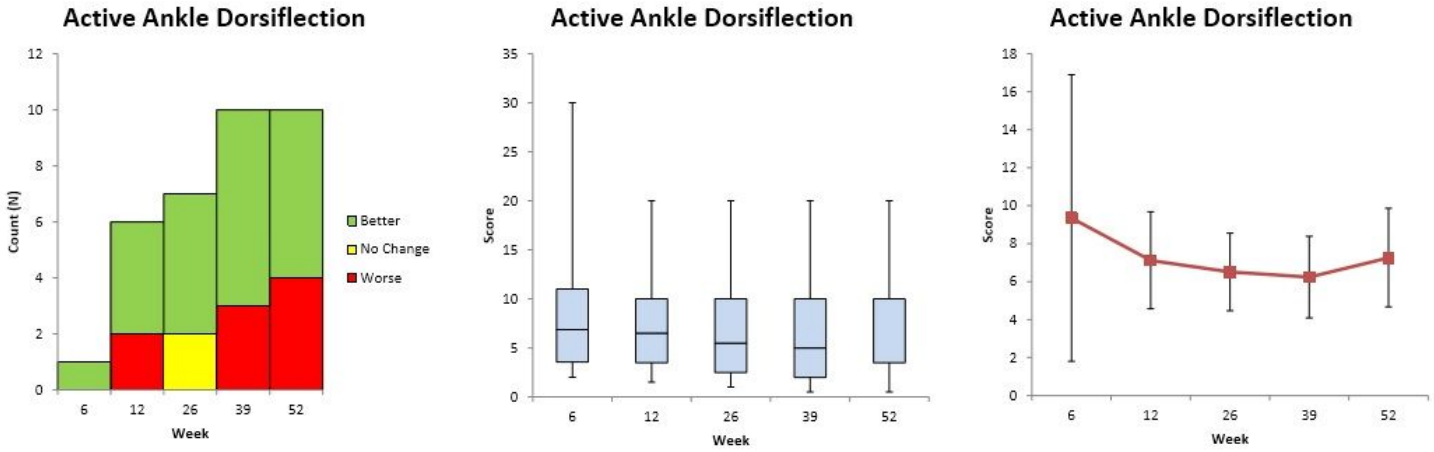

Figure 1

Active Ankle Dorsiflection (degrees)

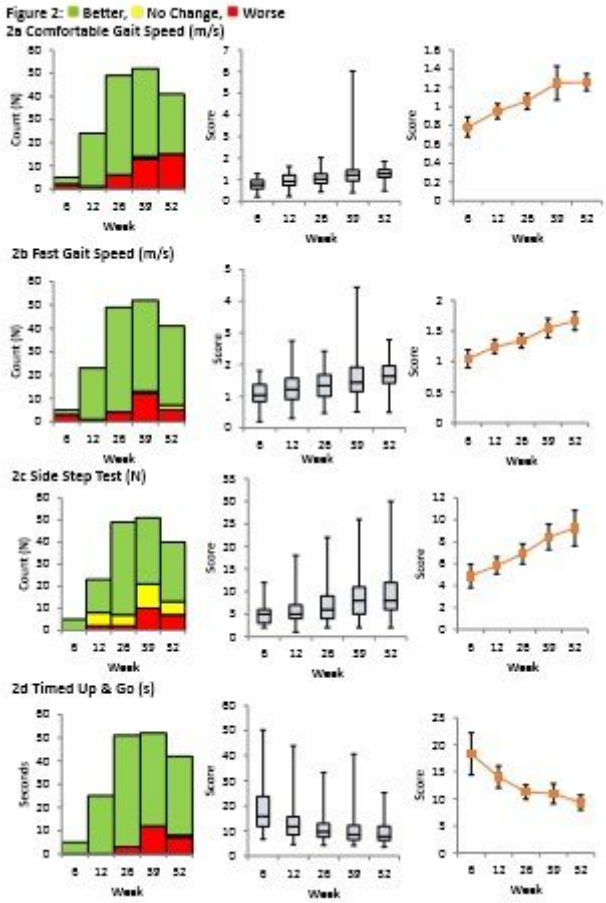

Figure 2

composite

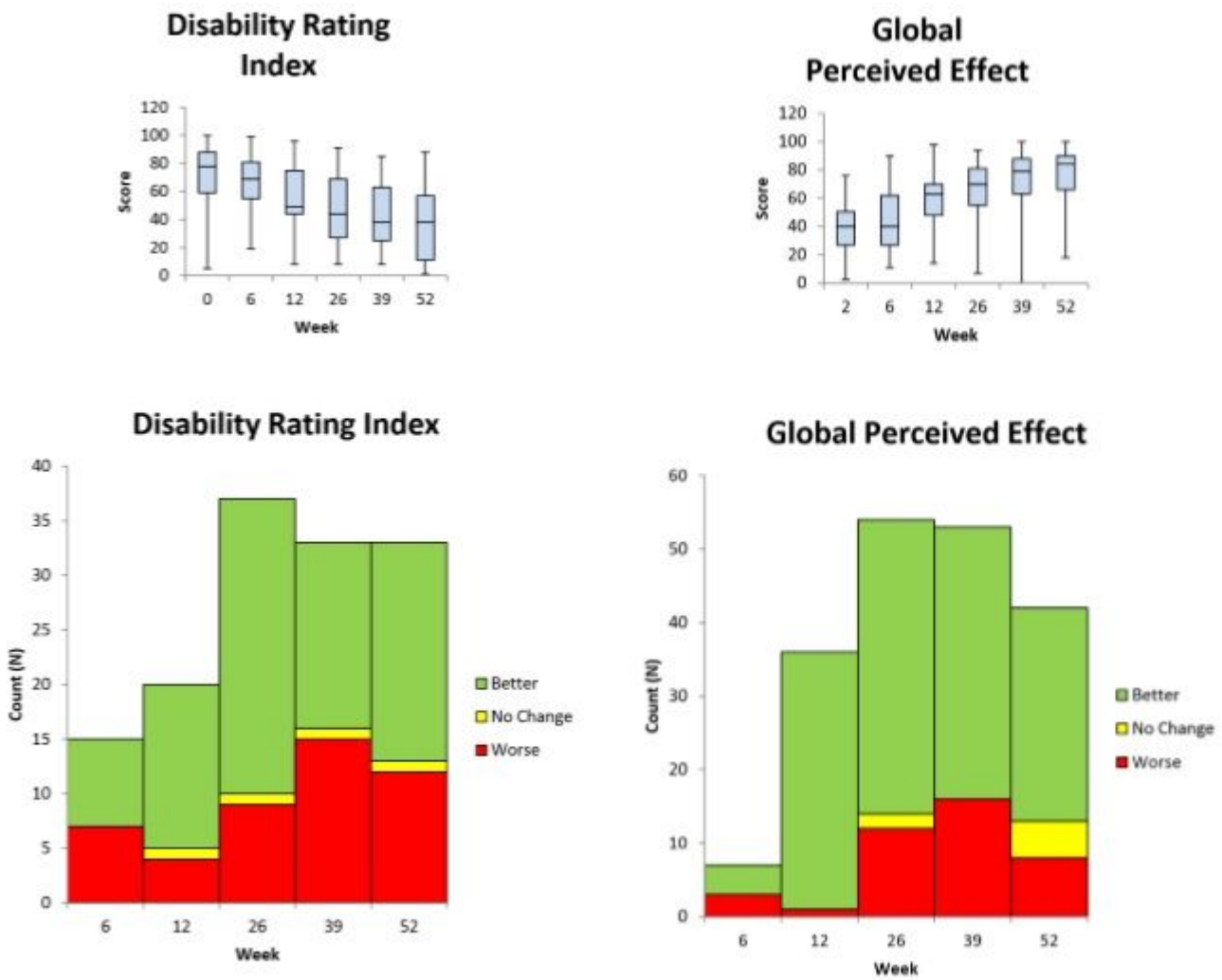

Figure 3

DRI & GPE final